REMARKS

Claims 1-20 are pending in the subject application. Claims 1, 9, 10, 15 and 20 have been amended for clarification purposes. Support for the amendment to claims 1, 9, 10, 15 and 20 is found throughout the Specification, as filed, and no new matter is presented by the amendment.

Favorable reconsideration in light of the amendments and remarks which follow s respectfully requested.

1. 35 U.S.C. §102 Rejections

Claim 9 has been rejected under 35 U.S.C. §102(b) as being anticipated by Yamada. The Office asserts that:

> Yamada teaches an intraocular lens 12 including an insertion and injection device 28 comprising an outlet member. The deflated lens 12 is mounted to the outlet member and includes a self-sealing mechanism 14/16 in which the insertion and injection device is removably and sealingly received such that the insertion and injection device can be removably and sealingly received in the self-sealing mechanism repeatedly, column 5, lines 39-52.

Applicants respectfully traverse this rejection.

Applicants claim in claim 9 an intraocular lens system comprising an insertion and injection device and a deflated lens member having an interior. The insertion and injection device comprises an outlet member and the deflated lens member is mounted to the outlet member. Further, the deflated lens member includes a self-sealing mechanism in which the insertion and injection device is removably and sealingly received such that the insertion and injection device can be removably and sealingly received in the self-sealing mechanism repeatedly. Further, the self-sealing mechanism is flush or continuous with the surrounding lens member.

As set out by Applicants, while intraocular lenses have been developed in which a deflated lens is inserted in the eye and the lens is subsequently inflated

or expanded by injecting a liquid, gas or other material into a cavity within the lens, these lenses are deficient for a number of reasons. For example, these lenses have been designed to include one or more separate conduits, cannulas or tubules extending through and out of the lenses. These conduits, cannulas or tubules interconnect the interior cavity to an external source of the liquid, gas or other material to be injected. Thus, with these lenses, the lens must be inserted into the eye, the lens must be inflated by flowing the liquid, gas or other material through the one or more conduits, cannulas or tubules into the cavity of the lens and, then, after inflation is completed, the connection with the external source is broken and the surgeon pushes the conduits, cannulas or tubules attached to the lens into a portion of the eye in which the lens is located. These conduits, cannulas or tubules present problems because they can occlude visual acuity even if the surgeon makes efforts to position the conduits, cannulas or tubules so as to minimize occlusion. (See page 3, line 28 – page 4, line 16)

Thus, Applicants have designed an intraocular lens system wherein the deflated lens member includes a self-sealing mechanism that is flush or continuous with the surrounding deflated lens member. In other words, Applicants deflated lens member does not include the conventional conduits, cannulas or tubules extending from the interior of the deflated lens member and outside of the deflated lens member. Thus, Applicants' device provides tremendous benefits in that the surgeon need not make the effort required to position conduits, cannulas or tubules so as to minimize occlusion of visual acuity since these conduits, cannulas or tubules are not present in Applicants device. Further, because these conduits, cannulas or tubules are not present, no potential for occlusion occurs.

The Yamada reference, on the other hand, specifically discloses and requires a tube protruding from the outer surface of the balloon member. Yamada describes an intraocular lens that includes a balloon member 12 and a tube 14 provided on the balloon member. The tube has a bore through which an optically transparent fluid is injected into the balloon member. The bore is filled with and fluid-tightly closed by a gel filler. The optically transparent fluid is injected into the balloon member through

the tube, with the gel filler inhibiting leakage of the fluid from the balloon member. (See Abstract; col. 2, lines 47-54)

As specifically set out by Yamada:

> The lens system 10 consists of a hollow balloon member 12, and a tube 14 which protrudes a suitable length from the balloon member 12. The tube 14 has a bore which communicates with the interior of the balloon member 12 and the exterior space, and which is filled with a gel filler 16. (Col. 3, lines 44-49)

Further,

> the length S of protrusion of the tube 14 as measured from the outer surface of the balloon member 12 is set to be about 2 mm or larger, preferably about 3 mm or larger, so as to facilitate the injection of the fluid from the outside of the capsular bag into the balloon member 12. (Col. 5, lines 13-18)

Thus, Yamada does not describe a self-sealing mechanism flush or continuous with the surrounding deflated lens member. Rather, Yamada specifically requires a tube protruding out of the balloon. This arrangement provides a number of disadvantages as set out by Applicants above. In particular, after the fluid is inserted into the balloon through the tube, the balloon must be carefully pushed into and positioned in the eye such occlusion of visual acuity due to the protruding tube is minimized. Further, according to Yamada, an additional step is required due to the presence of the tube:

> Upon completion of the injecting operation as described above, a portion of the tube 14 (which protrudes from the balloon member 12) is cut off by scissors, heat or a laser, for example. To more surely avoid the leakage of the fluid 18, it is possible to plug the tube 14 with a rod, for example, fitted in the tube 14, or by melting and sealing the tube 14 by means of a laser, for example. Where the fluid 18 consists of a material (e.g., polymerized silicone) which can be rapidly polymerized after injection, there is no need to seal the tube 14, in view of unlikelihood of leakage of the fluid 18 from the balloon member 12. (Col. 8, lines 1-12)

Applicants device, as set out above, does not include a tube. Rather, Applicants have designed a deflated lens member having a self-sealing mechanism that is flush or continuous with the surrounding deflated lens member. Fluid is injected into the

interior compartment of the deflated lens member through the self-sealing mechanism and, after injection of the fluid, the injection device is simply removed from the self-sealing mechanism. No tube is present and, thus, no occlusion of visual acuity occurs. Further, the surgeon need not take the additional steps of (1) carefully positioning the tube so as to minimize occlusion of visual acuity and (2) cutting a portion of the tube by, for example, scissors, heat or a laser. By eliminating the tube and the requirement for these additional steps, surgery time is reduced and the potential for additional complications is eliminated (e.g. damage to the eye due to the subsequent cutting step by scissors, heat or laser and due to the additional manipulation required to position the tube).

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suziki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicants respectfully submit that each and every element as set forth in the claim is <u>not</u> found, either expressly or inherently, in the cited reference. Thus, it is clear from the foregoing remarks that claim 9 is not anticipated by the Yamada reference.

2. <u>35 U.S.C. §103 Rejections</u>

Claims 1-7 and 10-20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Yamada in view of Sahatjian. The Office asserts that:

> Yamada appears silent with regard to whether or not the catheter 28 is shielded by an outer tube during the insertion process however, such is well within the realm of the artisan of ordinary skill. In this art it is well known to have an outer catheter tube which covers and supports the smaller inner tube that contain the working member of the operation. Protecting the human tissue and the lens itself during a process is a

> conventional consideration when inserting objects within the body. There is no unobviousness in using an outer member for covering and protecting the lens during the insertion process. Balloon catheters are routinely inserted inside and outer tubular member during the insertion process and the same provision would be true here as well. Manipulating the deflated lens within a small opening within the human body would be true here as well. Manipulating the deflated lens within a small opening within the human body would require the same care. Sahatjian who teaches an outer member 30 that contains and protects the inner inflatable member exemplifies this function. It would have been obvious to one of ordinary skill in the art to modify Yamada to use a separate outer tube around the inner inflatable member as taught by Sahatjian to protect the human tissue and protect and guide the inflatable member to its destination.

Applicants respectfully traverse for the reasons set forth above regarding claim 9.

In particular, Applicants claim, in claim 1, an intraocular lens system comprising an insertion and injection device and a deflated lens member having an interior. The insertion and injection device includes a moveable member having an outlet port. The movable member is housed within an outer member. The deflated lens member is mounted about and to an end of the moveable member such that the deflated lens member is sealingly engaged with a portion of the moveable member so that the interior of the deflated lens member forms a compartment. The moveable member outlet communicates with the deflated lens compartment. Further, the deflated lens member includes a self-sealing mechanism in which the insertion and injection device is removably and sealingly received such that the insertion and injection device can be removably and sealingly received in the self-sealing mechanism repeatedly. Further, the self-sealing mechanism is flush or continuous with the surrounding lens member.

Applicants claim, in claim 10, a method for implanting an intraocular lens in an eye comprising mounting a deflated lens member about and to an end of a moveable member such that the deflated lens member is sealingly engaged with a portion of the moveable member so that an interior of the deflated lens member forms a compartment and such that an outlet port in the moveable member communicates

with the deflated member compartment; disposing an outer member about the moveable member; inserting a portion of the outer member within the eye; moving the moveable member from a first position to a second position, thereby deploying the deflated lens member; forming the intraocular lens by injecting an optical medium into the deflated lens member compartment when the moveable member is in the second position using the moveable member outlet port; wherein after the movable member is removed from the eye and the intraocular lens remains in the eye, one can re-insert an injection device into the intraocular lens and adjust the amount of optical medium in the intraocular lens.

Applicants claim, in claim 15, a method for treating one of aphakia or cataract of an affected eye, comprising: removing the impaired natural lens of the affected eye; mounting a deflated lens member about and to an end of a moveable member such that the deflated lens member is sealingly engaged with a portion of the moveable member so that an interior of the deflated lens member forms a compartment and such that an outlet port in the moveable member communicates with the deflated member compartment; disposing an outer member about the moveable member; inserting a portion of the outer member within the eye; moving the moveable member from a first position to a second position, thereby deploying the deflated lens member; forming an intraocular lens by injecting an optical medium into the deflated lens member compartment when the moveable member is in the second position using the moveable member outlet port; removing the movable member from the eye; and allowing the intraocular lens to remain in the eye, wherein the lens member includes a self-sealing mechanism that is flush or continuous with the surrounding lens member, wherein the movable member is removably and sealingly received in the self-sealing mechanism and wherein after the movable member is removed from the eye and the intraocular lens remains in the eye, one can re-insert an injection device into the self-sealing mechanism and adjust the amount of optical medium in the intraocular lens.

Applicants claim, in claim 20, a device kit comprising at least one insertion and injection device and a deflated lens member having an interior. The insertion and injection device includes a moveable member having a outlet port provided therein and

an outer member in which is disposed the moveable member. The deflated lens member is mounted about and to an end of the moveable member such that the deflated lens member is sealingly engaged with a portion of the moveable member so that the interior of the deflated lens member forms a compartment. Further, the moveable member outlet communicates with the deflated member compartment through a self-sealing mechanism in which the movable member is removably and sealingly received and wherein the self-sealing mechanism is flush or continuous with the surrounding lens member.

As set out above, Yamada does not describe a self-sealing mechanism flush or continuous with the surrounding deflated lens member as set out in Applicants' claims 1, 15 and 20. Rather, Yamada specifically requires a tube protruding out of the balloon. Sahatjian does not remedy these deficiencies in Yamada. Sahatjian describes a bodily sample collection balloon catheter. According to Sahatjian, a balloon is mounted on a catheter and is inserted into a blood vessel. A sample is drawn into the balloon and the entire device removed from the blood vessel. Sahatkian does not describe or suggest inserting a inflatable member into the body nor does it describe a self-sealing mechanism that is flush or continuous with the surrounding inflatable member.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 2142.

Yamada and Sahatjian, both alone and in combination, fail to teach or suggest all of Applicants claim limitations. Further, there is no motivation to modify the

references as required by Applicants' claims. Accordingly, claims 1, 15 and 20 are patentable over Yamada in view of Sahatjian. Claims 2-8 depend from claim 1 and, likewise, are patentable over Yamada in view of Sahatjian. Claims 16-19 depend from claim 15 and, likewise, are patentable over Yamada in view of Sahatjian.

Regarding claim 10, Yamada, as set out above, describes a device wherein a tube protrudes from the outer surface of the balloon member. An optically transparent fluid is injected into the balloon member through the tube. Upon completion of the injecting operation, a portion of the tube (which protrudes from the balloon member) is cut off by scissors, heat or a laser, for example. Further, to more surely avoid the leakage of the fluid, the tube may be plugged with a rod or by melting and sealing the tube by means of a laser, for example. Yamada does not describe or suggest a device or method wherein, after the lens is inflated and left in the eye, at a later date one can re-insert an injection device into the intraocular lens and adjust the amount of optical medium in the intraocular lens. Further, there is no motivation provided to modify Yamada as set out by Applicants. Still further, Sahatjian does not remedy these deficiencies.

Thus, claim 10 is patentable over Yamada in view of Sahatjian. Claims 11-14 depend from claim 10 and, likewise, are patentable over Yamada in view of Sahatjian.

Claim 8 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Yamada in view of Sahatjian and further in view of Michelson. The Office asserts that:

> Michelson teaches that haptics 20 can be added to the inflatable lens as desired. It would have been obvious to one of ordinary skill in the art to further modify Yamada to include haptics as taught by Michelson when it is desired to help secure the lens in place.

Applicants respectfully traverse this rejection for the same reasons as set out above regarding claims 9, 1, 15 and 20. As set out, Yamada and Sahatjian, both alone and in combination, fail to teach or suggest a self-sealing mechanism flush or continuous with the surrounding deflated lens member. Michelson does not remedy these deficiencies. Michelson describes an intraocular lens having a tubule portion 24

extending from the lens. Upon injection of the lens, the tubule is sealed by crimping or other suitable means (see col. 5, lines 1-2).

Thus, claim 1 is patentable over Yamada in view of Sahatjian and further in view of Michelson. Claim 8 depends from claim 1 and, likewise, is patentable over Yamada in view of Sahatjian and further in view of Michelson.

CONCLUSION

Reconsideration and allowance of claims 1-20 is respectfully requested in view of the foregoing discussion. This case is believed to be in condition for immediate allowance. Applicant respectfully requests early consideration and allowance of the subject application.

Applicants believe that no extension of time is required since this response is being filed before the expiration of the specified time period. Applicants, however, conditionally petition for an extension of time to provide for the possibility that such a petition has been inadvertently overlooked and is required. As provided below charge Deposit Account No. **04-1105** for any required fee.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

Respectfully submitted,

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